

STATE OF WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Service Prior Authorization Criteria

Dificid® (fidamoxicin) Prior Authorization Request Form

DIFICID is a macrolide antibacterial drug indicated in adults (≥18 years of age) for treatment of Clostridium difficile-associated diarrhea.

Prior authorization requests will be approved for if the following criteria are met:

- Confirmed diagnosis of Clostridium difficile infection with clinically significant diarrhea;
 AND
- 2. Prior treatment with vancomycin for ten (10) to fourteen (14) days with no response.

Recommendations for the Treatment of Clostridium difficile Infection in Adults

Clinical Definition	Supportive Clinical Data	Recommended Treatment	Strength of Recommendation/ Quality of Evidence
Initial episode, non- severe	Leukocytosis with WBC count ≤15000 cells/mL and a SCr <1.5 mg/dL	VAN 125 mg qid x 10 days, OR	Strong/High
		• FDX 200 mg bid x 10 days	Strong/High
		 Alternate if above agents are unavailable: metronidazole, 500 mg tid PO x 10 days 	Weak/High
Initial episode, severe	Leukocytosis with a WBC count ≥15000 cells/mL or a SCr >1.5 mg/dL	• VAN 125 mg qid PO x 10 days, OR	Strong/High
		• FDX 200 mg bid x 10 days	Strong/High
Initial episode, fulminant	Hypotension or shock, ileus, megacolon	• VAN 500 mg qid PO or NG. If ileus, consider adding rectal instillation of VAN. Metronidazole (500 mg IV q8h) should be administered together with PO or rectal VAN, particularly if ileus is present.	Strong/Moderate (oral VAN); Weak/Low (rectal VAN); Strong/Moderate (intravenous metronidazole)
First recurrence		 VAN 125 mg qid x10 days if metronidazole was used for the initial episode, OR 	Weak/Low
		 Use a prolonged tapered and pulsed VAN regimen if a standard regimen was used for the initial 	Weak/Low



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Clinical Definition	Supportive Clinical Data	Recommended Treatment	Strength of Recommendation/ Quality of Evidence
		episode (eg, 125 mg qid x 10–14 days, bid for a week, qd for a week, and then every 2 or 3 days for 2–8 weeks), OR	
		FDX 200 mg bid x 10 days if VAN used for initial episode	Weak/Moderate
Second or subsequent recurrence		VAN in a tapered and pulsed regimen, OR	Weak/Low
		VAN 125 mg qid PO x 10 days followed by rifaximin 400 mg tid x 20 days, OR	Weak/Low
		• FDX 200 mg bid x 10 days OR	Weak/Low
		Fecal microbiota transplantation	Strong/Moderate

Abbreviations: FDX – fidaxomicin, VAN – vancomycin, WBC - white blood cell count, SCr - serum creatinine, PO - by mouth, NG - by nasogastric tube, tid - three times daily, qid - four times daily

References

- 1. LexiComp monograph for fidaxomicin (Dificid) (reviewed 7/11/2018)
- 2. Guidelines for diagnosis and management of Clostridium difficile infection (March 2018)
 - Clinical Infectious Diseases, Volume 66, Issue 7, 19 March 2018, Pages e1–e48, https://doi.org/10.1093/cid/cix1085